ORIGINAL

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

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IRON WORKERS LOCAL UNION :

NO. 17 INSURANCE FUND, et al., :

Plaintiffs, :

v. : Civil Action No.:

PHILIP MORRIS, INCORPORATED, : 1:97 CV 1422

et al., :

Defendants. :

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Washington, D.C.

Monday, November 23, 1998

Deposition of ROBERT D. VERHALEN, a witness herein, called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to agreement, the witness being duly sworn by JAN A. WILLIAMS, a Notary Public in and for the District of Columbia, taken at the offices of Shook, Hardy, & Bacon, LLP, Suite 600, 801 Pennsylvania Avenue, N.W., Washington, D.C., at 10:15 a.m., Monday, November 23, 1998, and the proceedings being taken down by Stenotype by JAN A. WILLIAMS, RPR, and transcribed under her

direction.

APPEARANCES:

On behalf of the Plaintiffs:

RICHARD G. PICCIONI, ESQ.
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On behalf of the Defendant Lorillard Tobacco Company:

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ALSO PRESENT:

WILLIAM J. THOMPSON

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EXHIBITS

PROCEEDINGS

Whereupon,

ROBERT D. VERHALEN,

was called as a witness by counsel for Plaintiffs, and having been duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION BY COUNSEL

FOR PLAINTIFFS

BY MR. PICCIONI:

Q. Would you please state your name for the record.

A. Robert D. Verhalen.

Q. Dr. Verhalen, my name is Richard Piccioni, I'm one of the attorneys for the plaintiffs in this case. I'll be taking your deposition today. And I know you've had your deposition taken before, correct?

A. Yes.

Q. And I know you're familiar with the procedure. But just to be sure, if there's anything that I ask that is in any way unclear, will you agree to not answer those questions but rather ask me to rephrase them?

A. Yes.

Q. What is your understanding as to whom you are to bill for your time here today?

A. Well, I usually just send my bill directly to Shook, Hardy & Bacon.

Q. And how late are you prepared to stay today for this deposition?

A. Well, my understanding is that you're allowed seven hours. So I'm prepared to stay seven hours from whenever our beginning time was.

Q. Which was ten o'clock.

A. Right.

Q. Your preferences about taking a break at lunch?

A. I really don't have a preference, we can have something brought in, we can take a short break.

Q. Fine.

A. But at my age I need an occasional head break.

Q. Okay, fine, just let me know. Did you bring any documents with you today?

A. I brought my report.

Q. And what was your understanding about the document request that accompanied this?

A. Well, I have not seen a subpoena for

this particular session so I didn't bother bringing anything else. But, going on the basis of history with the last testimony, I believe that it was not necessary to bring anything that was from published sources or that you already had. So that's the premise I'm operating under.

Q. Are there any notes or any other materials that you developed in the course of preparing for your testimony or preparing that report?

A. No.

Q. Doctor, when were you first contacted about testifying in the Ohio case, the Iron Workers case?

A. Gee, I checked all the dates on this. Probably a month or six weeks ago.

Q. And who contacted you about that?

A. I was contacted by Shook, Hardy & Bacon attorneys.

Q. Who in particular?

A. Probably Keith Borman.

Q. You are also an expert witness in the Northwest Laborers case?

A. That's correct.

Q. And I take it you were contacted about

testifying or appearing as a witness in the Ohio case after your deposition in the Northwest Laborers case?

A. It may not have been after the deposition. I can't remember the exact dates, but somewhere around there. Probably just before that deposition.

Q. How much time have you spent on preparing for the Iron Workers case? I'll refer to it as the Ohio case.

A. Okay. I really don't know exactly because I was working on another case up until the time that it was stayed. I could only guess.

Q. Go ahead and guess.

A. Perhaps 100 hours.

Q. What did that work entail generally?

A. Well, the entire 100 would not necessarily have been me. I have staff who will pull documents for me. So some of that would be them. But pulling documents, reviewing the documents that were prepared by the plaintiffs' witnesses, and then preparing my report.

Q. The report which you prepared in this case, is it related to the report which you

prepared in the Northwest Laborers case in the sense that information in the former was used in the latter?

A. To a substantial extent, that's true.

MR. PICCIONI: If we could mark as Exhibit 1 Dr. Verhalen's report in the Ohio case.

(Verhalen-Ohio Exhibit No. 1 was marked for identification.)

BY MR. PICCIONI:

Q. Could you look at your report on page 7. The last full paragraph on that page, the last sentence of that paragraph, if you could read that sentence.

A. The same would hold true?

Q. Yes.

A. For circumstances in which decisions were to be made about who owes what to whom for real or imagined grievances such as in the current action regarding the Ohio Insurance Fund's payments for treatment of smoking-related diseases in the northwest. I'm sorry. In the northwest was a carryover from the previous report.

Q. Also, in the following paragraph,

there's a sentence that begins with the word plaintiffs, plaintiffs in this action. Could you read that one.

A. Plaintiffs in this action, however, seek damages for at least the 28 period 1979 to 2007.

Q. That was 28-year period?

A. Yes.

Q. And what was the basis of that time period?

A. I would have to go back and look at the report. It's entirely possible this is a typo also carried over. What I did was I took my Northwest report, made a copy of it, and then made the changes necessary to produce this report, adding in what I felt was necessary. Now, I thought I had corrected all these, but I would have to check the report.

Q. And that process that you just described did not involve the printing and hand-editing of the Northwest Laborers report?

A. Sometimes I will do that when I've completed the report and then I'll go through and do a hand-editing process. Why I wouldn't have picked this up I'm not quite sure. But then I'll

just destroy the hand-edited copy. The only copy I keep is my electronic version.

Q. Did the process that you describe involve any form of communication with defense counsel?

A. No, it did not.

Q. Do you have a copy of Appendix B to this report with you?

A. I don't have it with me. Appendix B was the article by -- on the ICD-9. I don't have that attached to my copy. Again that was from a published source.

Q. Doctor, have you ever taught a course in epidemiology?

A. Not in epidemiology per se, no, I have not.

Q. Statistics?

A. No.

Q. Have you published any papers describing original research in the field of epidemiology?

A. No, I have not.

Q. Have you served on the editorial boards of any epidemiological journals?

A. No, I have not.

Q. Sat on the thesis committee of a graduate student in epidemiology?

A. Not in epidemiology, no.

Q. In any other field?

A. Yes.

Q. What field was that?

A. In health administration.

Q. Have you reviewed grant applications for funding for epidemiological research?

A. Yes, I have.

Q. When was that?

A. That was through the mid to late eighties and perhaps into the early nineties, maybe '90, '91.

Q. For what granting agency?

A. For the Centers for Disease Control.

Q. What study section was that?

A. This was for the Center for Injury and Violence Prevention. I was on the committee dealing with epidemiologic studies.

Q. Doctor, can you explain to me the difference between a confounder and an effect modifier?

A. A confounder and an effect modifier? If I understand you correctly, that effect

modifier would be design effect, is that what you're talking about?

Q. How about effect of an exposure?

A. Well, I'm not familiar with the term in that context. Effect modifier as an effective exposure?

Q. Well, if you think of -- I'm trying not to answer the question.

Are you familiar with the term noncollapsibility as it applies to odds ratios?

A. Not as it applies to odds ratios, but in a generic sense I am.

Q. Could you explain to me what that term means in a generic sense.

A. Noncollapsibility is when a -- would be when a data stream or a set of data have been gathered in a very specific sense but may have overlapping or nonmutually exclusive categories, you cannot collapse them into smaller groups for purposes of comparison or analysis.

Q. What's a multiplicative interaction?

A. A multiplicative interaction would be one in which there are more than a single influence on a particular disease category. There may be, for instance, a variety of causes

or presumed causes of a particular condition, any one of which may by themselves, in an additive or in a multiplicative sense, exacerbate the problem; synergy, if you will.

Q. Are both additive and multiplicative interactions considered synergistic?

A. Not necessarily. They may be. Multiplicative frequently are.

Q. If you have a multiplicative interaction between two exposures, what is the relationship between the relative risks for each exposure and both exposures?

A. That's difficult to say. It would relate largely to the degree to which the various influences are associated. If they are multiplicative in a very, very strong sense, two to one, three to one, four to one, one has a much stronger synergy on the other, it might have an exacerbating effect; if it were in the reverse, it may have an ameliorating effect.

Q. Can you give me an example of two exposures that interact in a multiplicative manner?

A. I haven't given it any thought. Sitting here it's a little difficult to come up

with one right offhand.

Q. If exposure A interacts in a multiplicative way with exposure B, does the relative risk for A change in the presence of B?

A. It might, yes.

Q. Doctor, do you regularly attend conferences in the field of epidemiology?

A. When I can get away.

Q. Which is how frequently?

A. In the last couple of years, I have not.

Q. Couple meaning?

A. Meaning since '95, late '95.

Q. And prior to that?

A. I used to try to attend regularly.

Q. Do you know personally people who you think of as being well-recognized epidemiologists?

A. Yes.

Q. Could you name some of them.

A. Sure. Vernon Houk.

Q. Anyone else?

A. I'm trying to think of the new dean of the School of Public Health at Chapel Hill, he used to be the head of the Centers For Disease

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Control. Bill Roper.

Q. Anybody else?

A. Brian McMahon. I mean we could go through a litany here. How many do we want to name?

Q. Kenneth Rothman?

A. I'm not familiar with Kenneth Rothman.

Q. Sander Greenland?

A. I've heard the name, but I'm not familiar with it.

Q. Demitrious Trichopoulos?

A. No, I'm not familiar.

Q. David Savitz?

A. David Savitz I know.

Q. Dr. Fraumeni?

A. Yes, by reputation.

Q. But not personally?

A. Not personally.

Q. Have you collaborated with any of these people that you've named in research projects?

A. Not directly, no.

Q. I understand, Doctor, that you were the director of epidemiology at the CPSC from 1972 to 1995; is that correct?

A. That's correct.

Q. Does that post still exist?

A. Yes, it does.

Q. Who is the present director?

A. I do not know her name, it just -- when I left the agency, they collapsed two organizations. And they brought a woman in who is basically a laboratory scientist. And she is the director of epidemiology.

Q. That makes sense I suppose.

A. Not to me. Politics.

Q. Does the CPSC consider cigarettes to be consumer products?

A. Yes and no. There's not a clear answer to that. Tobacco was explicitly excluded from the Consumer Product Safety Act. But, under the Secretary for Health and Human Services, when they wanted to look at a fire safe cigarette, the CPSC was given the lead by The White House I believe in setting it up. So to that extent CPSC was involved in cigarettes as a product, but just with respect to flammability.

Q. What is the role of epidemiology in the operations of the CPSC?

A. The charter for the directorate for epidemiology in CPSC was embodied in Section 5 of

the act in which it stated the commission shall establish and maintain a clearinghouse to collect, investigate, and analyze injury and illness information as related to products. So, as the director of epidemiology, I led the organization which did those four functions.

Q. What would be the purpose of collecting such information?

A. To identify areas for further research to get at the causes of injury.

Q. How would you -- strike that.

Can you give me an example of that purpose being served in the case of a particular product for which epidemiological studies were done by the CPSC?

A. Sure. When we noticed a fairly large number of injuries associated with chain saws, we identified cases through our surveillance system for follow-up to determine exactly how the accident occurred; at which point, after accumulating a number of investigations, we were able to identify kickback as one of the major scenarios leading to serious injury and death.

And that led to the development of laboratory tests of various chain saws which went

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beyond the epidemiology. Now we had identified where the basic problem was.

And the laboratory then took that information to identify exactly -- or to design a study to test exactly how much kickback came from different types of chain saws with different types of chains under different conditions which we had identified for them as potentially relevant.

Q. Did I hear this right, that the epidemiological study of chain saw accidents led to the identification of kickback?

A. Led to the identification of relevant circumstances in the accident that warranted direct study to see exactly how the injuries occurred and what could be done to prevent them.

Q. So I'm just remembering wrong, that I thought you said identified kickback as the occurrence that was leading to the injuries?

A. Well, as one of several relevant scenarios that led to injury.

Q. Kickback leads to injury?

A. Not inevitably. I'm sorry.

Q. You didn't hear the word if in the beginning of that.

A. Okay.

Q. I'm sorry. How did you determine that kickback led to injury?

A. We conducted investigations of a sample of chain saw-related injuries which were reported to us from hospital emergency rooms. When we conducted those investigations, we saw -- we learned what events took place immediately before leading up to the event itself and immediately after to -- so that we had a relatively good picture of what happened.

In some of these cases, a kickback was -- figured prominently as one of several causes of injury which were being treated in the emergency rooms. As a consequence of that, we decided that kickback warranted a closer look to see exactly how it occurred, under what circumstances it occurred, and tried to get a handle on how often it occurred without injury as well as with injury. That was a laboratory function.

They instrumented chain saws and took high-speed videotapes with chain saws being used by professionals under a variety of circumstances and were able to determine what kinds of chain

led to the strongest kickback, what kinds of chain saws, models and brands, had the strongest kickback, and made several judgments as to which might have been the greatest -- the strongest factors in leading to kickback that would be sufficient to actually kick back far enough to hit the user, the operator.

And that led then to a number of other experiments into different kinds of low kickback chains in an effort to reduce the extent of kickback. You couldn't prevent it entirely, but you could reduce it.

Q. I'm interested really in the very beginning of that answer.

A. Sure.

Q. The part that involves the epidemiological methods. I take it that you looked at several instances of accidents involving chain saws?

A. Hundreds.

Q. And you developed a statistical association between what?

A. Various accident scenarios and injury by severity of injury and type of injury.

Q. The presence or absence of kickback was

determined how?

A. By direct investigation and questions of the victim or bystanders.

Q. As in the chain saw kicked back, a description like that perhaps from the injured person?

A. Yes, or my foot slipped and the log allowed the chain to go down and hit my foot. Kickback was not the only kind of injury, it was just one of the most frequent.

Q. Was there a statistical association between the occurrence of kickback and the severity of the injury?

A. No, nor would I have expected there to have been. You don't measure events that don't lead to injury in a situation such as we had here. We had a surveillance system which involved hospital emergency rooms reporting to a central source.

And kickback occurs literally hundreds of times any time one uses a chain saw. They don't necessarily lead to injury. Just as many things occur, feet slip, people trip, and so on, they're not necessarily injured.

In cases where they're injured, we

simply listed them by frequency of injury and severity of injury in any particular scenario and decided where we would focus our energies first to get at the details that led to kickback.

Q. You mean, every time that a chain saw kicks back, it doesn't cause an injury?

A. No.

Q. But sometimes it does cause an injury?

A. It depends on the position and attitude of the operator, how high the chain saw kicks back, whether it kicks back typically 20 degrees under full power or 30 degrees or 40 degrees and where it hits him, if at all. In some cases kickback may cause the chain saw to go very high, but the person is able to avoid it as it comes up.

Q. In your preceding answer, you said something like under certain circumstances kickback leads to injury?

A. Yes.

Q. In my question I asked you if kickback always caused injury. Is there a difference between the word leads to and cause?

A. No, I don't think so.

Q. So, going back a couple of questions,

are you saying that you used epidemiological studies to determine whether kickback led to injuries with chain saws; am I correct?

A. No, to determine how kickback led to chain saws. First what kinds of injuries were associated with the use of chain saws; of the kinds of injuries that were associated with chain saws, which seemed to lead to the most serious kinds of injuries or the most frequent injuries; and, having identified those by surveillance or descriptive epidemiology, if you will, we passed it on to the engineers who then took the accident scenarios and designed laboratory experiments to get at exactly how kickback led to injury.

Q. But the epidemiological studies persuaded you to some level of confidence that kickback led to injuries?

A. Was one source of injuries.

Q. That kickback caused injuries?

A. Kickback could cause injuries.

Q. That kickback increased the risk of injury?

A. That kickback -- without kickback there would be no risk of injury from kickback, but there would be other injuries. Kickback was just

one type of injury.

Q. That measures taken to prevent kickback would decrease the incidence of injury?

A. It would decrease the incidence of kickback injury.

Q. Based on epidemiological studies?

A. Yes.

Q. What are the characteristics of epidemiological findings, say, those in particular you could use as an example, if it's helpful in answering the question, that are persuasive in leading to an inference of a cause-and-effect relationship?

A. In the product safety area in which we were operating, cause-and-effect relationships were pretty clear on the surface of them when you conducted an investigation. A, you either had an injury in association with a chain saw or you did not; B, if you had an injury with a chain saw, it occurred in one of several different ways; C, if you ranked these ways, you can decide which ones you want to put your next dollars on to determine exactly how and why those events are occurring; D, once you've identified the ways they are occurring and developed remedial measures and

implemented those remedial measures, following sufficient time for the market penetration of the changes to occur in new products, you should see a decline in that type of injury from that particular cause.

Q. And those are all epidemiological observations?

A. In the product safety area, yes. Let me correct that last statement. When you said they're all epidemiological observations, all except the laboratory portion. Everything leading up to the laboratory portion and then evaluating the effect of the laboratory portion is descriptive of epidemiology.

Q. Doctor, is it safe to say that the goal of the CPSC is the introduction of safer products into the U.S. market?

A. No. The goal of CPSC is to reduce injuries associated with consumer products.

Q. Is one of the ways that that goal could be achieved that there be changes in product design that improve the safety of products?

A. Yes.

Q. Can you give me an example of a product that exists now that existed 25 years ago and is

in some respects safer than it was 25 years ago, the same product but somehow safer?

A. Chain saws is one example.

Q. Are there products that are less safe than they were 25 years ago?

A. In what context? After having taken action based on CPSC action?

Q. Just can you think of a product, something that I would go into a store and buy, that in some respects is less safe now than it was 25 years ago?

A. That's difficult to answer the way you've phrased it.

Q. Can you identify the difficulty in the phrasing?

A. Well, product life is a highly variable entity. And some products which have a fairly long life in use such as roller skates will modify over time in such a way that they are still basically the same product, but there are sufficient differences in them as a result of modern technology that they're used in a different context which makes them more unsafe.

Q. Thank you. That actually helps me understand. I had an example in mind, sofas.

Sofas, and correct me if I'm wrong, on a market share basis, now are more likely to be filled with polyurethane foam padding rather than some kind of cellulose-based padding. And I understand, and correct me if I'm wrong, that in some respects polyurethane foam presents certain safety issues or presents them in a way which is more problematic than older cellulose fill?

A. That may be. I'm not personally familiar with the characteristics of polyurethane foam or cellulose. I expect you're speaking with respect to flammability?

Q. Yes.

A. And off-gassing. I know there are issues, I don't know exactly what those issues are. I would be more inclined to use an example like roller skates which have morphed into Roller Blades which puts them in a different environment. They are much higher speed.

They're still basically roller skates, but now they're in-line skates. I said Roller Blades, that's a trade name, I should say in-line skates. And they tend to be used more often in the situation which leads the user into conflict with automobiles and other kinds of problems.

And I consider them less safe than the old sidewalk roller skate.

Q. Plus kids today are out of their minds, right?

A. Well, that's your characterization, not mine.

Q. Are cigarettes safer than they used to be 25 years ago?

A. I can't answer that question, I really don't know.

MR. DUNCAN: Objection to the form of the question, lack of foundation.

THE WITNESS: I guess the premise that cigarettes were unsafe is one that might be raised here. Whether or not I would agree with whether or not they were unsafe, they certainly are not safer from a flammability standpoint because I know that's what we had looked at at CPSC.

There has been no change in the propensity for ignition of upholstered furniture. But that's as much a problem with the furniture and its flammability as it is with the source of ignition.

BY MR. PICCIONI:

Q. Doctor, I understand that, since retiring from CPSC, you are working under the auspices of an organization called Verhalen & Associates; is that correct?

A. That's correct.

Q. What kind of work does that organization do?

A. Basically we do research into hazards that people ask about that are within our area of competence. And we had started out originally as product safety and helped people to understand what the data that are collected by the federal government mean and what they do not mean.

Q. When you say people, can you give me an example without revealing anything that's of proprietary nature of the kind of person that you're talking about?

A. Sure. Anybody who has a need to understand what the data with respect to products that are put out by the Consumer Products Safety Commission mean and what they don't mean. In some cases those may be manufacturers, in some cases they may be trade associations, and in some cases they're researchers who are trying to work with the data and they're not quite sure how to

get it, and we show them how to get it and how to interpret it.

Q. Are they ever defendants in products liability suits?

A. Yes, they are.

Q. If you were to apportion the fraction of the work that's performed by Verhalen & Associates into that which is performed in connection with a products liability suit and that which is not, what would that mix be?

A. Probably 90 to 95 percent would be in association with some kind of a product liability suit, you know, probably 90 to 95 percent.

Q. And within that portion can you tell me what fraction of it is work that is being paid for by defendants in products liability suits as opposed to plaintiffs?

A. I would say 75 to 80 percent.

Q. Does the work on products liability suits ever entail offering an opinion about whether a product defect was a cause of injury?

A. Not quite exactly that way. It generally tends more to be whether or not a particular product characteristic is in some way causally associated with an injury.

Q. In those cases in which you are providing services for the plaintiffs in a products liability case, have any of those situations involved work such as you just described in your previous answer; that is, work in which a characteristic of the product is shown to have a causal association with an injury?

A. Yes.

Q. Can you give me an example of that?

A. The one case I'm involved in here is on hold at the moment, it's still in litigation, and I really can't discuss the product without revealing the industry.

One that is not on hold but it's early enough that I can get into it probably without revealing it involves not a consumer product in the normal sense but a medication in this particular case, tetanus toxoid, and Guillain-Barre syndrome, where the defendant is trying to claim that a particular case of Guillain-Barre syndrome was not the result of tetanus toxoid.

On the basis of epidemiologic rarity, I contend that epidemiology cannot be used in this context to say that it is not associated any more

than it could be to say that it was associated. But the potential exists. And it involves an organization within the government which is supposed to be responsible for making payments to persons who have been injured by the use of inoculation or immunization shots.

Q. Can you think of another example?

A. As I said, the only one I can think of -- the only other one I can think of is in sort of a sensitive stage right now of development.

Q. But at least --

A. Actually there are two of them there in development now that I think about it.

Q. But at least in principle I as an attorney might come to you and say review the epidemiological literature concerning a drug and incidence of an adverse medical condition because I represent a person who developed that condition after taking that drug. That such a request -- this isn't a sentence, but such a request would fall within the ambit of the kind of work that your organization might do?

A. It might be a part of it. It would kind of depend on what it is they asked me to

do. Usually they're asking me to give them some kind of an opinion on what the literature says about a particular situation.

But it's not -- it's not like they can get me to review it from one perspective. I'll review the literature critically and here's my opinion. And that has led to the loss of some clients.

Q. So maybe a better example would be that I come to you as an attorney and ask you whether you think that a causal relationship between taking the drug and the injury is supported by the epidemiological evidence?

A. A question could be phrased that way. Generally I'm not approached by someone who says do you think that such and such is true. I generally get a situation where they come in and -- well, let me use as an example snowblowers, where I was asked to review the data that had been available over the past 15 years on snowblower-related accidents and render an opinion as to how I think those accidents are occurring insofar as the data will permit me to render that opinion.

After I did that, it did lead to

further work in that area, where they asked me to try to collect additional information on snowblowers.

Q. I take it in that instance there was some feature of snowblowers that was at issue?

A. Not so much a feature of snowblowers but a type of injury, finger amputation.

Q. And snowblowers generally?

A. Snowblowers generally.

Q. Where was the epidemiology?

A. Well, I didn't characterize that as an epidemiologic inquiry. But you asked me what kinds of things could you as a lawyer come and ask. And these are among the things that you could come and ask.

The epidemiology would be probably in the second stage, where we begin doing some primary data collection of our own on the distribution of snowblowers with certain features that the data showed to be associated with finger amputation.

MR. DUNCAN: It's been about an hour and a half. I wonder if this might be an appropriate time for a break.

(Recess.)

BY MR. PICCIONI:

Q. Doctor, when we started the break, I was asking you about the kind of work that Verhalen & Associates performs or could be expected to perform on behalf of a plaintiff in a products liability suit. And my question is really this, under what circumstances, circumstances related to the epidemiological literature dealing with a certain hazard, under what circumstances would you render an opinion that that epidemiological literature was supportive of a cause-and-effect relationship between a hazard and an injury?

MR. DUNCAN: Objection as to form.

THE WITNESS: I'm honestly not certain I followed the question. Under what circumstances would I render an opinion whether or not the epidemiological literature supported an association?

BY MR. PICCIONI:

Q. Supported a causal association.

A. Difficult to answer that in a vacuum. A causal association requires a lot more than just epidemiology. To my mind causal association requires also demonstration of the cause and

effect controlling for other known potential causes, not just epidemiologically, because there are a variety of things that you can't control in the epidemiological context except statistically. That has its own limitations. So I really can't answer that question.

Both my batteries are going bad at the same time here.

MR. DUNCAN: You want to take a break?

THE WITNESS: No. We'll go along while they're still working.

BY MR. PICCIONI:

Q. Can epidemiological observations increase the likelihood that a cause-and-effect relationship exists between an exposure and disease?

A. May I repeat the question to make sure I understand it. Can epidemiological observations increase the likelihood that a causal relationship exists? No.

MR. DUNCAN: Excuse me. I wonder if we can just go ahead and take a break.

(Discussion off the record.)

BY MR. PICCIONI:

Q. Have you ever rendered an opinion about

whether something is likely to be true?

MR. DUNCAN: Objection as to form.

THE WITNESS: In any context?

BY MR. PICCIONI:

Q. Any context.

A. Sure.

Q. Have you ever rendered an opinion about whether a cause-and-effect relationship likely exists?

MR. DUNCAN: Objection as to form.

THE WITNESS: I guess I probably have at some point. I can't think of one right now. But where a causal relationship probably exists, again in any context, I'm sure I have.

BY MR. PICCIONI:

Q. Do the findings of epidemiological studies -- strike that.

Are there circumstances under which the findings of epidemiological studies can contribute to your forming the opinion that a cause-and-effect relationship probably exists?

MR. DUNCAN: Objection as to form.

THE WITNESS: Not to the extent of the use of the term probably. I would be more inclined to say that epidemiologic data could

reach the point that I would say it may exist and it requires further investigation.

BY MR. PICCIONI:

Q. And by probably are you referring to the likelihood being greater that the proposition is true than that the proposition is false?

MR. DUNCAN: Objection as to form, that misstates his testimony.

THE WITNESS: I didn't say probably. I said not to the extent of probably. I said that the epidemiologic literature could lead me to the conclusion that a relationship -- a causal relationship may exist. I would not say probably because to me the term probably carries with it a little more definitive judgment than I think epidemiology is capable of making by itself.

BY MR. PICCIONI:

Q. If I take an ordinary legitimate pack of cards and I remove from the pack ten diamonds, I reshuffle the pack thoroughly, the remainder of the pack thoroughly, is the card on the top of the deck probably black?

A. It will have -- I'm trying to remember the numbers in cards. We're talking 52 to a deck, you're removing ten fifty-seconds of the

reds, I have to do the numbers. It might be more likely to be black than red because there are more black cards. I can't give you the exact figure without doing the arithmetic.

Q. Just so we're on the same wavelength as far as the meanings of words that mean different things in different contexts, when I use the word probably, I simply mean what you just said, that it's more likely true than not true.

MR. DUNCAN: Objection as to form.

BY MR. PICCIONI:

Q. Does that help you answer my question?

A. Well, if that means that it's more likely true than not true but not necessarily more than 50 percent likely, yes, I can accept that. It's a standard probability equation.

Q. If I take a deck of cards, a standard legitimate deck of cards, and I remove a single diamond, shuffle thoroughly, is the card that turns up on the top of the deck probably red?

A. No, not necessarily.

Q. Is it more likely than not to be red?

MR. DUNCAN: Objection as to form.

THE WITNESS: You would be reducing the likelihood of a red by taking out a red.

BY MR. PICCIONI:

Q. Is it more likely to be black?

A. In a strict probability sense, it's more likely to be black, one fifty-second more likely or somewhere around there.

Q. So epidemiological evidence standing alone could never persuade you that a cause-and-effect relationship is more likely true than not true?

A. No, because in virtually every context I can think of, with a few exceptions in the product safety area where it's clear a chain saw causes an evulsion in a particular case, you're dealing with a variety of unknowns that have also been shown to be associated with the same phenomenon. Therefore, I personally do not believe that epidemiology by itself can lead to a competent conclusion that a causal relationship probably or is more likely to exist.

Q. But a body of epidemiological evidence could move your judgment in that direction; that is to say, in the direction of believing that a cause-and-effect relationship probably exists?

MR. DUNCAN: Objection to form.

THE WITNESS: No. It would increase

the likelihood of my belief that a causal relationship may exist. But the whole premise of epidemiology, when you're looking at data, is that all else being equal.

And, with epidemiologic data, when you're dealing with populations, you generally don't have the precise measures you need on everybody in that population to get to that point.

BY MR. PICCIONI:

Q. So one epidemiological study with a relative risk of 1.2 with a confidence interval between 0.8 and 1.8 is as persuasive as 100 epidemiological studies with relative risks that are never less than ten?

A. More persuasive in what?

Q. In your reaching an opinion that a cause-and-effect relationship probably exists.

MR. DUNCAN: Objection as to form.

THE WITNESS: Again the premise here is that I can be convinced that a cause/effect relationship probably exists from a body of epidemiologic data. And I'm trying to get across to you the fact that epidemiologic data by themselves, regardless of what the relative

effects are and regardless of the number of studies, convince me only that a causal association may exist.

Until I can demonstrate that by knowing what the confounders are and physically controlling for those confounders, ruling them out as potential causes within the population, I'm no more convinced than I was before. I would be convinced of the potential that a causal relationship may exist only, not on the probability.

BY MR. PICCIONI:

Q. But your conviction that the potential exists might be stronger if the epidemiological evidence was as I described in the second example?

A. My conviction that a causal relationship may exist would be stronger with replication, yes.

Q. And strength of association?

A. And strength of association, but not definitive.

Q. Am I correct in understanding that what you need further beyond epidemiological results is an understanding of mechanism?

A. Yes. But that's not all I need.

Q. What else?

A. I would want epidemiological data that demonstrates the presence or absence of the other potential causes in that population and the degree to which they are present.

Q. But that's epidemiological data, those are epidemiological associations, correct?

A. That's true.

Q. Which are obtainable not just in principle but in the real world?

A. For the most part, they are if you're willing to spend the time and money to gather them. But it also requires that you conduct your study on the population of interest, not on a surrogate population, unless you can assure that the surrogate population is, in fact, representative.

Q. If I'm confining myself to the population upon which the epidemiological study was actually conducted to a situation in which the epidemiological evidence includes investigation of potential confounders --

A. All known potential confounders and suspected confounders.

Q. To be sure. And the association that is observed is strong and any other indicia that you would like to mention, all within the sphere of epidemiological evidence, is it only mechanism that is missing?

MR. DUNCAN: Objection as to form.

THE WITNESS: When you get to this point, you're moving to that gray area between epidemiology and clinical medicine that accounts -- that is known as case control studies, where you have the information on the population, now you want to know how that applies to the individuals within that population.

Then you have all the information you need, you have the epidemiological information, you have the clinical information on the individuals and their individual exposure rates, then you can make a positive determination.

But you are really into that gray area, you're really having to go slightly beyond epidemiology into clinical medicine, because you've got to bring it down to the individuals or some representative sample of those individuals within that population for whom you are taking actual measurements on those potential

confounders, be they exposure to other toxins in the environment or habits that may also be confounders or gene pools, if you've got the genetic history or the medical history of the individual families. All of those go into making up the necessary body of data to make a definitive statement about cause and effect.

BY MR. PICCIONI:

Q. Even a statement being made about whether a cause-and-effect relationship is more probably true than not true?

MR. DUNCAN: Objection as to form.

THE WITNESS: I'm not certain how to answer that. If you have this body of epidemiologic information on the precise target population that you're looking at and on all of the confounders, you could probably come down to a statement of more likely true than not true or probably true. But you would still have to check it.

BY MR. PICCIONI:

Q. How can you ever be sure you know about all the confounders?

A. Well, by reviewing the literature, you can know about all known or potential confounders

that have been identified. Then it simply becomes a matter of finding a way to measure it.

Q. Can't someone always come up with another potential confounder?

A. Conceivably, yes. That's a problem. And that's why I said you really have to go beyond epidemiology to be definitive.

Q. To be definitive or to render an opinion that a cause-and-effect relationship is more likely to exist than not?

A. Certainly to be definitive. It would really be a judgment call in any case as to whether or not you want to say more likely than not at that point. I tend to err on the side of conservative. I prefer to see things definitively spelled out.

In population data you are dealing with populations, groups of people. And not all of them are going to react exactly the same to any particular influence. We've just been alluding to confounders in the sense of potential causation so far or at least implicit in our conversation. There are also confounders that may be protective.

(Discussion off the record.)

BY MR. PICCIONI:

Q. I'm handing you a copy of your expert report in the Minnesota case. Does this report bear some relation to the report that you prepared in the Northwest Laborers case and the Ohio case?

A. Well, not directly. I mean some of it obviously is covering some of the same ground.

Q. On page 10 there is a section beginning with the words less convincing. Do you see that?

A. Uh-huh.

Q. If you could look at your report in the Ohio case, beginning at page 5. Sorry, beginning at page 7. And the section on page 7, where it starts with the heading Logical & Scientific Flaws, we start with the words in public health present in both reports.

If we look in the Ohio case, the second to the last sentence there ends population to be served. And, if we look in the Minnesota report, we can also see text ending in the sentence population to be served.

A. Sure.

Q. In the Ohio case, there is one more sentence, and then the start of a new paragraph

beginning in situations. In the Minnesota report, there is a section --

MR. DUNCAN: Objection as to form. Are these questions?

BY MR. PICCIONI:

Q. I'm implying, when I'm making these statements, the question are you following me when I'm pointing to each of these sections of text. Is that clear?

A. I'm not quite sure where you're going with this. I mean I plagiarize myself obviously, I say I'm covering the same ground, in some cases I've used some of the same structure I've used before, in others I've added to it, I've modified it, I've grown with it. I'm not sure what your question is.

Q. In the Minnesota report, there is a section beginning less convincing and running through the end of that paragraph.

A. Okay.

Q. Is that language in your Ohio report?

A. It may be, it may be identical, it may be slightly modified. Do you want me to read the both of them and see?

Q. If you can take a minute or two.

A. Sure. If I had some idea what your question was going to be, I could read it with that in mind.

Q. Why don't you see whether it's present in the Ohio report.

A. The thrust of it is the same. I think I added a little more. It's not identical. I'm not sure, how far do you want me to read on this?

Q. Am I wrong that the entire section starting with the word too, t-o-o, too often --

A. I was starting at far less convincing.

Q. It's the next sentence.

A. Well, the next sentence in which one, in the Minnesota?

Q. In the Minnesota.

A. All right. Too often, right.

Q. Am I correct that that entire section, running from that sentence to the end of the paragraph in the Minnesota report, is absent from the Ohio Iron Workers report?

A. Yes, it appears to be.

Q. Do you remember deciding to delete that section?

A. I don't remember specifically why or

when I decided to delete it. What I usually did was I read through previous reports to see what was usable in the future, made notes to myself, and then wrote, if possible, pretty much from scratch.

Sometimes, if I covered things in a slightly different context, I struck them out completely in the earlier one. There's really not a nefarious purpose to it, it's just that, in trying to put the thing together as a coherent whole, I wrote it the way I wrote it.

Q. I certainly wasn't suggesting the purpose was nefarious, I was just trying to understand.

A. Well, that's why I was wondering if I could have some idea of what the question was, it would have been helpful when I read through it rather than having to go back then again and see, because I was obviously misinterpreting what sentence you were beginning with and so forth.

In any event they're related in the sense that they cover some of the same ground. They're unrelated in the sense that each one is an independent report.

Q. Looking at that section that we

identified which was deleted from the Minnesota report in creating the Northwest Laborers report which was the progenitor of the Ohio report --

MR. DUNCAN: Objection as to form.

BY MR. PICCIONI:

Q. -- is there anything about the content of these sentences that is not true any longer or does not apply?

A. No.

Q. Is not true in the context of the Ohio case?

A. No, I don't think so. I think I just covered it in a somewhat different fashion, that's all.

Q. Doctor, is it your understanding that the National Medical Expenditure Survey database is relied upon by any expert in this case as a source of data on exposure or expenditures?

A. I think it's relied to in a sense. The disease rates themselves come from the Surgeon General's report. And the smoking data comes from the Health Interview Survey. But the NMES itself is not to my knowledge directly involved in the computation. I'd have to go back and check, but I don't think it is.

Q. Would NMES have been a more reliable source for information about exposure or expenditures than the data relied upon by plaintiffs' experts in this case?

A. I don't think it would be more reliable. I think it has problems of its own, that there are a number of difficulties when you're dealing with national databases on subunits of that national population. And I have explored that to some extent in this report.

Q. This report meaning the Ohio report?

A. The Ohio report.

Q. Am I correct that it's explored to a greater extent in the Minnesota report?

A. I don't think so. It may or may not be. I talk about the synthetic estimation process. It's not a minor problem, it's I consider a major problem.

The amount of space I give to it is not necessarily indicative of the importance compared with something else that may have more space. It probably has more to do with my ability to articulate my argument when I was writing it.

Q. How about the problem of self reporting of health status?

A. No less important now than it ever was.

Q. So it's important to the use of and reliance upon NMES data?

A. That's correct. It's also important to the use or reliance on Health Interview Survey data.

Q. Would the problems in using NMES to make reliable estimations of the relationship between smoking history and expenditure be solved by confining the analysis to a subset of the NMES population?

A. No, for the reason that the NMES population was a national population. If I could put this in the context of the surveillance system we had at CPSC which I developed, it was a national sample. And we had hospital emergency rooms reporting on a daily basis all product-related injuries treated in their emergency rooms.

Now, if the state of California which had perhaps six hospitals in the system out of 91 total wanted to know anything about injury problems in their state, we could not simply take the California contingent of hospitals and draw

any conclusions for California based upon those because they were not designed as a statistical subset of California hospitals. Each hospital in the system was part of a national system.

But with NMES it was a national sample, it was not designed to be used at the state or lower level. Like most national systems, the best you can do is bring it down to perhaps region, one of the four census regions.

Q. Suppose you were to confine or someone were to confine their analysis to those participants in the NMES study who obtained their health insurance from a union insurance fund. Would that data be reliable as a source of information on the relationship between smoking and disease as it exists in trust funds in Ohio?

MR. DUNCAN: Objection to the form.

THE WITNESS: No, I do not believe they would be.

BY MR. PICCIONI:

Q. How about if the population were restricted to participants in the NMES study who described their occupation as construction workers. Would results obtained from such a subpopulation of NMES provide a reliable basis

upon which to make statements about the relationship between smoking and expenditures in the Ohio Trust Funds?

A. I don't believe they would, no.

(Verhalen-Ohio Exhibit No. 2 was marked for identification.)

BY MR. PICCIONI:

Q. I'm handing you a couple of pages from the 1989 Surgeon General's report, Chapter 3. And I'd like you to look at table 6 at page 150. Are you on that page?

A. I am.

Q. The last number in the second column, the column headed Current Smokers?

A. Current Smokers.

Q. Yes.

A. Okay.

Q. Can you explain to me the relationship between the number that's not in parentheses and the numbers that are in parentheses?

A. The number not in parentheses is essentially a mean value. The number in parentheses is the 95 percent confidence interval which means there is an equal likelihood it could be at the lowest number or the highest number.

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Q. So, if we go over one column to the right there and we see another estimate, another set of numbers, a value 1.9 with a confidence interval of 1.28 to 2.82?

A. Which one are we looking at now?

Q. Former smokers.

A. But which one are you looking at, the bladder cancer?

Q. Yes, the last row. That's compared to the previous value we were talking about which was 2.86 with a confidence interval of 1.85 to 4.44. From a statistical point of view, are those two means different?

A. I don't think they're identified as statistically different. They may be. I'm not sure how they're -- certainly there's a difference.

Q. Terrible question. Is the difference in the means of these two observations statistically significant at the 95 percent confidence level?

MR. DUNCAN: Objection as to form.

THE WITNESS: There's nothing here that indicates it is a statistically significant difference that I can see offhand. But the error

margins overlap considerably. So the likelihood of statistical significance reduces commensurately.

BY MR. PICCIONI:

Q. So, when you say the error margins overlap considerably, you mean that's because the lower limit of the value for current smokers, 1.85, is less than the upper limit for the value for former smokers of 2.82?

A. Considerably less, yes.

Q. Is that a general principle of statistical methodology, that two observed means aren't statistically significantly different if the lower limit of the confidence interval of the higher value is less than the upper limit of the confidence interval of the lower value?

MR. DUNCAN: Object to the form of the question.

THE WITNESS: No, it's not a general principle. It's sort of a rule of thumb that you can use when you're glancing at things. You subject them to a statistical test of differences. There are any one of a variety of tests that one could use.

BY MR. PICCIONI:

Q. But, if someone were to come forward and say that these two means are different, would you be supportive or unsupportive of such an assertion?

MR. DUNCAN: Objection as to form.

THE WITNESS: I don't think I would be one way or the other. I would look at it and ask myself whether or not I wanted to subject this to a statistical test.

BY MR. PICCIONI:

Q. What kind of statistical test?

A. There are a variety of tests you could use, you could use an analysis of variance, you could use a student's T or a Z test, any one of a variety of tests that may be applied. I am not a statistician.

But a statistician has a number of tools at his disposal, none of which are exactly always correct. It's up to the judgment of the statistician which one he wants to use. But I would generally defer to a statistician.

Q. But it would be methodologically problematic in your mind to conclude that there is a difference between these two means absent other information when the confidence intervals

overlap; is that correct?

MR. DUNCAN: Object to the form.

THE WITNESS: No. I don't have a problem with saying there's a difference between the two means. I can see the difference, 2.86 to 1.90. The significance of that difference is problematic only in the sense that there is not an indication that they are statistically different.

When there is no such indication, the first thing that occurs to me is they are not statistically significant, they are different. And, when I see overlapping confidence intervals, it enhances the notion that this really should be subjected to a test for differences. The fact that they didn't overlap wouldn't necessarily lead me to not bother with wanting a test, I would still want a test.

Q. Doctor, what part of the CPS II study is based on self reporting?

A. Actually it's really all based on self reporting because people are drawn into the system by volunteers who then interview them. And what they're getting is all the information they gathered was gathered from the individuals,

it was not gathered from a third source, any administrative records or anything of that nature.

Q. Cause of death was determined -- was self reported?

A. Well, certainly was self reported initially because nobody had a record of their death until the next cycle of the interview and they said, well, Sam died, and then they were able to get ahold of the record if they required it. I don't know that they did.

Q. You don't know whether cause of death in CPS II was determined from looking at death certificates; am I correct?

A. Ultimately the cause of death that was recorded was from the death certificate. But the initial indication of the fact of death was on the part of the self reporting.

Q. Do you know if the death certificates in the CPS II study were reviewed for errors?

A. I don't personally know, but I doubt that they were, because that would have required going back to the medical records to look. In most cases what we were dealing with is not the deaths but morbidity rather than mortality.

Deaths were certainly a part of the CPS II study, but there was -- a large part of CPS II was dealing with morbidity situations, people who had disease conditions that they reported to the interviewer.

Q. We're talking about the Cancer Prevention Study part II?

A. Yes, that's correct.

Q. Conducted by the American Cancer Society?

A. That's correct.

Q. What is or are the documents that describe that study that you looked to for information about it?

A. I had a series of documents that were the original questionnaires that were used by the interviewers in CPS II which I had gotten on my own request from Shook, Hardy & Bacon. But my concern was not with the accuracy of the data so much as with the precision of the data. I'm sorry, the representation of the data.

I do have a concern with CPS II as it relates to the use of the ICD-9 codes because ICD-9 coding is always subject to clerical error. These codes, whether they're taken to the

first, second, or third decimal place, can get fairly complex. And clerical errors are common.

Q. Do you still have these documents that you obtained?

A. I probably do. I haven't seen them in sometime, but they're probably somewhere around the office.

Q. And they form in part a basis for your opinions about the CPS II study?

A. Well, certainly they -- yeah, they must have. I looked at them fairly early on, long before we got into this. So, for whatever knowledge I have on CPS II, that's where it would come from.

Q. And it would be possible to locate those documents and make copies of them?

A. Certainly.

MR. PICCIONI: I'd like to request that we do so.

MR. DUNCAN: Is there a notice and request for documents in conjunction with this deposition, do you know?

MR. PICCIONI: My understanding is there is an agreement.

MR. DUNCAN: Okay.

MR. PICCIONI: To produce documents which are not published upon which the witness relies as a basis for his testimony.

(Discussion off the record.)

(Verhalen-Ohio Exhibit No. 3 was marked for identification.)

BY MR. PICCIONI:

Q. Doctor, I'm handing you a copy of an article I've had marked as an exhibit. The authors are Percy, et al. Is this one of the articles that you list among the references in the back of your report in the Ohio case?

A. I think so. Yes.

Q. Am I correct that you cite this article as providing support for the proposition that miscoding of ICD-9's as the underlying cause of death could be a source of error in the CPS II study?

A. As one of the arguments, yes.

Q. Does this study by Percy, et al., present data from participants in the CPS II study?

A. No, I don't believe it does. It simply uses Third National Cancer Survey. And it seems to me this is an NIH. Yes.

Q. Is it from a period of time that overlaps the study period of the CPS II?

A. No. Really it's between CPS I and CPS II.

Q. Is it the same -- strike that.

Does the population studied in this paper have the same age structure as the CPS II study population?

A. I didn't review with that in mind. That was not the point of the citation. The point of the citation was the accuracy of the ICD codes.

Q. But am I wrong in concluding that you believe that this research described in this study is applicable in some sense to potential problems in the CPS II study?

A. Methodologically, yes.

Q. If you look at table 3 on page 246 of the Percy report, and we look at the row that's labeled 162 for the ICD-8 category, so they're using here ICD-8 versus ICD-9 in CPS II; am I correct?

A. That's correct.

Q. But the results of this study are, nevertheless, useful in considering potential

methodological problems in CPS II, correct?

A. Yes. The ICD coding itself is what the focus is in this article. ICD-7 was used in the first CPS study, ICD-8, and then ICD-9 was used in the last study. ICD-10 has just been published.

Q. Going back to the line that begins at 162, in the second numerical column, am I correct that that is a count of the number of cases in which lung cancer was listed as the cause of death on the death certificate?

A. That's correct.

Q. And the preceding column is the number of cases in which lung cancer was listed as the cause of death based on the hospital records?

A. Well, that was the diagnosis in the hospital.

Q. Thank you. So that I could obtain the number of times that the cause of death on the death certificate was listed as lung cancer when the hospital diagnosis was not lung cancer by taking the difference between the second column and the first column; is that correct?

MR. DUNCAN: Objection as to form.

THE WITNESS: I think that's correct,

yes.

BY MR. PICCIONI:

Q. Now, can you do that arithmetic for me?

A. You mean the -- the 10,059 from the 178?

Q. Yes.

A. It's 118 -- 19.

Q. Excuse me. So it's 119 cases out of how many?

A. Out of roughly 10,000.

Q. If we look at table 2 on page 244 and go down to the row that starts lung plus and then the next column is 162, am I correct that skipping the next column which has the value 10,059 and adding up the numbers in each subsequent column up to 161, the column labeled 161, and then continuing the addition with the column labeled 160 to 163, proceeding all the way across the page, I'll get the total number of cases in which the hospital diagnosis was lung cancer, but the underlying cause of death listed on the death certificate was not lung cancer?

A. As long as you leave out column 162, that's correct.

Q. If I add up those numbers and they are

greater than the difference between 10,178 and 10,059, am I right in concluding that the apparent errors in the coding of cause of death for lung cancer led to fewer cases of lung cancer identified as the cause of death on the death certificate than if those apparent errors had not been made?

A. No. Of the 10,059 diagnosed within the hospital, 9,560 were actual lung cancer or at least appeared on the death certificate. But remember that, if you go down 163, column 163, you've got a number of cases that appeared on the death certificate as lung cancer which were not, the hospital diagnosis was something other than lung cancer.

Q. Do you mean column 162?

A. Yes, I'm sorry. Yes, 162. My finger slipped over one. If you go down column 162, you find that 22 cases, for example, that appeared on the death certificate as lung cancer were actually diagnosed in the hospital as buccal cavity cancer, 13 were esophageal, ten were stomach, 25 were colon, nine were rectum, et cetera. You have to look at this in both directions.

MR. DUNCAN: Would this be a good place to break?
MR. PICCIONI: Just one minute.
BY MR. PICCIONI:
Q. On table 3 there's a column entitled Confirmation Rate. What's your understanding as to what that value is that's presented?
A. That 93 percent of the death certificates labeled as 162 were actually 162.
Q. Actually meaning according to the hospital?
A. Had been diagnosed in the hospital as 162.
Q. And the column to the left of that is the Detection Rate. What's your interpretation of the meaning of that value?
A. I hadn't really looked at detection rate. I don't know, I would have to go back into the article.
Q. Okay. Could it be that that is the percentage of cases in which the hospital diagnosis was lung cancer and the cause of death listed on the death certificate was also lung cancer?
MR. DUNCAN: Objection, asked and

answered.

THE WITNESS: I can read you the definition from the text. "The detection rate for a specific site was defined as the number of cases diagnosed as cancer of that site in the hospital and having cancer of the same site on the death certificate divided by the total number of persons diagnosed with that specific site of cancer in the hospital and dying of cancer. It is, therefore, the proportion of hospital diagnoses with cancer of a certain site in which the cause of death reflects the same hospital diagnosis."

MR. PICCIONI: Why don't we go ahead and have some lunch.

(Whereupon, at 1:05 p.m., the deposition in the above-entitled matter was recessed, to reconvene at 1:50 p.m., this same day.)

AFTERNOON SESSION

(2:00 p.m.)

Whereupon,

ROBERT D. VERHALEN,

the witness on the stand at the time of recess, having been previously duly sworn, was further examined and testified as follows:

EXAMINATION BY COUNSEL

FOR PLAINTIFFS (RESUMED)

BY MR. PICCIONI:

Q. Doctor, if you can look at Exhibit 1 which I believe is your report in the Ohio case, and at page 10, actually starting on page 9, the very last sentence that begins on that page and continues over to the next one, I'm having a little trouble understanding those two sentences.

The first sentence and the second sentence of that paragraph, are they both supposed to be there; that is, are they saying something different as opposed to saying just the same thing twice?

A. No. I think the second sentence is simply explaining the first sentence.

Q. Okay.

A. And I'm not always the most efficient writer.

Q. So the reference standard, if you will, that's here, am I correct that it's a reasonable level of epidemiological certainty?

A. That the information is correct.

Q. Can you tell me more about what you mean by a reasonable level of epidemiological certainty?

A. Well, something beyond the 60 percent that's alluded to in the Bright article, probably up in the neighborhood of 90, 95 percent would be comfortable. It's to that that I also address myself to the fact that, if you've got a large population, you might be better off taking a good statistical sample rather than trying to do 100 percent of a census.

Q. The 90, 95 percent value you just cited refers to what exactly?

A. Concordance between reality and what was on the code, if you were to check the medical record to ensure that it and the ICD-9 code refer to the same disease condition.

Q. And that value determined to what level of precision?

A. I don't follow your question there.

Q. You speak here about the possibility of using statistical sampling, am I correct, in estimating that concordance value?

A. Oh, I think that it would be reasonable to probably set that at the 95 percent level; that, if you take a sample that would give you an estimate within 5 percent of the true figure, at the 95 percent confidence level, that I would probably be comfortable with that, that the information is sufficiently accurate to be used.

I mean these are values that would have to be determined as you're going into it. Certainly any competent statistician could design a study that would provide that or a sample that would provide that.

Q. So that, if I understand this correctly, and correct me if I don't, the estimate that came out of this analysis was that there was a 95 percent concordance. And that estimate ranged between 90 percent and 100 percent in the 95 percent confidence interval?

A. Yeah. Actually the higher the better. I have not thought through exactly what the

sample design should be or the level. But 60 percent is clearly too low. And you've got to do something.

That suggests to me that the data should be cleaned up; in other words, amended; that, as you go through the data and you find discordance, that it would be corrected to whatever the diagnosis should have been and will not be subject to random clerical error or any other kind of clerical error.

Q. Are you saying that the concordance rate in this population was 60 percent?

A. In the Ohio population?

Q. Yes.

A. No, I'm not. I don't know what it is. But I venture neither do your own analysts.

Q. That's the figure that appears in the Bright paper?

A. That's correct. They have found in their review that there was an accuracy level of 60 percent.

Q. Which is --

A. I'm sorry, inaccuracy level of 60 percent.

Q. And that was a study of what kinds of

populations?

A. That was Medicaid claims data that they had reviewed. I offhand don't recall which state, I would have to look at the paper again.

Q. Have you formed any opinions about the necessary segregation of subpopulations within the Ohio Trust Fund beneficiary population that would have to be sampled separately?

A. Oh, I think each group would have to be sampled separately because each comprises a different population which may have systematic differences from another, especially in terms of their use of the medical benefits available to them.

Q. By each group you mean each trust fund?

A. Yes. I don't have a list here of what they are, there are five or six trust funds I think.

Q. Within each trust fund, would men need to be analyzed separately from women?

A. No. I think you can take a statistical sample of that population. And, as long as it is representative of the mix by age and sex, that would be adequate. Again I would leave that to the statisticians.

Q. And that also pertains to the issue of what the diagnosis was or the putative diagnosis was, also that you would not need to separately analyze subgroups with different diagnoses?

A. I would think not, because we're not talking here about systematic errors as a function of diagnosis. We may be, but that's not what I was driving at here.

I was driving principally here at just clerical error which in themselves are problematic. If there's a potential or any suggestion that there is a systematic error introduced by problems of definition, then that raises another question. But I hadn't raised that question.

Q. You're concerned about simply random miscoding?

A. It may be random. If you could be assured that it was purely random, then perhaps it's not so bad, everything would wash out. But there's no way to know that it's random. It may be a function of the breadth of the code, some ICD codes are broader than others.

Q. Do you have any opinion about the size of the sample that would have to be taken?

A. No, I don't.

Q. Do you have an opinion about whether the information that you would be seeking could be obtained from the medical records as opposed to examination of the recipients themselves?

A. No, I don't, except in the instance where there may not have been a physician's diagnosis, I don't know that that would fit here. But, if someone were making a claim absent a physician's diagnosis, then you certainly would want to know if that individual was properly characterizing his condition. I expect that's a much less frequent kind of problem, but it should certainly be looked at.

Q. Why is it that a random sample across these subpopulations of men and women, different age categories, different diagnostic categories, would be adequate; but a random sample across those categories and funds would not be?

A. I'm not sure I understand the question. Why is it that a random sample across men and women overall would not be adequate, whereas a random sample of men and women within a fund would be, is that what your question is?

Q. Not exactly. You said, if I recall

correctly, that you thought each fund would have to be analyzed separately; but that within each fund the men would not have to be analyzed separately from the women, a random sample of the total population within the fund would be good enough.

A. Okay. That's pretty much -- I can't say it really wouldn't be adequate. I don't know that it wouldn't be adequate. It would depend on the degree to which the population covered by any particular fund is suitably representative of -- the population were fundamentally the same as the population in the other funds.

If you have a fund which is made up of predominantly more educated white collar type of people associated with the union as opposed to those who are perhaps less educated, working in the field, then they constitute quite different populations. And it would probably be best to at least discriminate between those two kinds of funds, because you have fundamental differences in the types of individuals who make up the population group.

Q. But you haven't been asked, Doctor, to develop such a method?

A. No, I have not.
Q. Do you have an opinion, if necessary in the context of parameters that we might be able to specify, about the magnitude of such an undertaking?
MR. DUNCAN: Objection as to form.
BY MR. PICCIONI:
Q. Let me clarify. Magnitude would be basically dimensions of time and dollars.
A. I don't have a formed opinion. I do know that it would take some time and resources. But I don't have an opinion as to whether we're talking about days or weeks. But I don't think it should be much more than that as a dedicated effort.
Q. You've had experience obtaining medical records from healthcare providers and conducting examinations of individual people?
A. I have -- I have had experience getting records from medical care providers and directly from people, yes, when we've interviewed people as well, yes.
Q. And what do you have in mind as a number, if you do have one, of these individual investigations that would have to take place when

you say it would be days or weeks, not months?

A. I don't have an idea of numbers. But, if you've got data available and you were to go to a sample, if the size of the population were simply too large to do a census and you went to a sample, you could draw a sample that would probably be in the hundreds per unit and allow you then to base some estimates and corrections.

But it would pretty much depend on how large the errors were and where those errors were. It's kind of feeling your way. But a dedicated effort I think would be unlikely to be months. It may be, but I just don't think it would be. We did it at CPSC on more than one occasion within less than six weeks and we were dealing nationwide.

Q. How many individuals were part of the study?

A. We probably -- I'm trying to think back of what our first study was back in the late seventies. It was probably close to 60 or 65,000 individuals that were actually contacted.

Q. Any idea of the cost of that study?

A. Yeah, I think back then it was around 50 to $60,000. So you might say 100 to $150,000

today. I'm guessing, I'm not really in a
position without sitting down and trying to cost
it out what it would involve.
Q. One dollar or two per subject?
A. It depends on the ability to get at the
records and who you've got doing it and how much
you have to move people around. I'm really --
I'm really not in a position to make a competent
estimate for that. If somebody were to ask me to
do the study, I would have to sit down and cost
it out. It would probably take me a day or so to
cost it out.
Q. Doctor, in your Ohio report, page 4,
maybe you can help me here. Somewhere in your
report you make the statement or something like
the following statement, that it's unsound to
attribute to smoking diseases that are only
aggravated by smoking?
A. Yes. On reflection -- let's see here.
Here it is, the third bullet point from the
bottom. Mr. Roberts had suggested including
estimates of cost for treating conditions
aggravated by smoking rather than just conditions
that were caused by smoking. But I'm not quite
sure where in the document that was, I'd have to

go back and review it.

Q. Could you give me an example of a disease that would be like that?

A. Asthma conditions, for example, which drove an asthma sufferer back to a physician for additional treatment, for example.

Q. So suppose you have two populations of asthmatics. One population smokes, the other doesn't smoke. And suppose that, in the smoking asthmatic population, there are more visits to the doctor for the treatment of asthma. That is not caused by smoking?

A. It may or may not be. There are a lot of other conditions that go along with smoking within families, indoor air pollution itself is an aggravating condition and smoking exacerbates that.

How much of an asthmatic sufferer's additional suffering is due to smoking, how much of it is due to indoor air pollution partly as a result of smoking, partly as a result of otherwise pollutants within the internal atmosphere, it's just something that would require a separate treatment I think if you were to try to get into that and actually document

what proportion of the seeking of treatment is actually due to the aggravated condition as opposed to the condition as it would have been had there not been a smoker in the home for an individual.

I mean just taking classes of treatment for people, asthmatic sufferers, is not in itself sufficient to know that, anymore than it is to judge the occurrence of asthma to smoking.

Q. But if you are comparing like populations with regard to any other relevant exposures or predisposition, the only difference then being smoking, why wouldn't the difference be attributable to smoking?

A. Because you've got someone who is already under treatment for a particular condition. And they may go to that condition -- go to their physician for treatment more often for a variety of reasons other than due to the actual exacerbating effects of smoke itself simply because they're not feeling well. They may have a completely different way in which they relate to the healthcare system.

You cannot easily separate out the portion of whichever kind of treatment they would

seek which was a direct result of smoking for these individuals. And, therefore, I think it's silly to try to add that on.

Q. But, if the two populations are the same in every respect except for the smoking and the smoking population has more visits to the doctor --

MR. DUNCAN: Objection, asked and answered.

BY MR. PICCIONI:

Q. -- how could the difference not be attributable to smoking?

A. As I said it may be more a function of just general comfort level than it is actual exacerbation of the condition. It doesn't necessarily mean the condition is made worse. But the individual may be more apt to go off to a physician simply because he finds his environment less pleasant and he's seeking treatment.

Q. In my hypothetical is it true that but for smoking in my hypothetical as you understand it, is it true that but for smoking the expenditures of the two populations would be the same?

A. They might be, yes.

Q. In the hypothetical situation where but for smoking the expenditures of the two asthmatic populations would be the same, is the difference between the expenditures of the smoking population and the nonsmoking population attributable to smoking?

A. It may be. But again I can only say that there are -- when people are suffering various levels of discomfort, if there are more among them who will have a proclivity to seek treatment that is not necessary simply to ease their comfort level, not because the condition itself has necessarily worsened, but simply as a matter of course to -- it's like people who go to the physician when they don't need to just because it sets their mind at ease.

We're talking about conditions that are not necessarily caused by but simply make the individual less comfortable. It doesn't necessarily require medical treatment, but he seeks medical treatment.

Q. In the example that you're giving, it's the smoking that makes the individual less comfortable?

A. Yes. Let me put it in a different

context.

Q. Well, actually I would prefer if you just sort of answered the question at this point.

MR. DUNCAN: Objection, that question has been asked and answered several times.

BY MR. PICCIONI:

Q. You can answer.

A. Give me your question again.

Q. The question is whether the condition that you were speaking to as causing people discomfort which led them to go to the doctor more often, are you talking about smoking as being that condition which causes them to go to the doctor more often?

A. It could be. The context in which you put your question to me was whether or not, if smoking -- if asthmatics in smoking households had a higher medical cost for treatment of their condition than those in nonsmoking environments, would that be attributable to tobacco. Did I understand your question correctly?

Q. That's close enough.

A. It may be associated with the smoking. However, whether or not they actually require

treatment because of the additional discomfort is an open question. Frequently people will go to treatment simply to ease discomfort which doesn't necessarily require medical treatment, they just feel more comfortable by having received it. And that's why I wanted to try to put it in a slightly different context for you.

Q. Are you saying that the only time higher expenditures in smoking -- excuse me, higher expenditures for a smoking population compared to a nonsmoking population can be attributable to smoking is if smoking is the only cause of the higher expenditures?

A. Close. I have to put it in a slightly different context in order to make clear what I mean. If you have fraud in a system, for example, and there is an extra amount of treatment that is sought due to fraud and that fraud is related in some way to smoking, I would not consider that a legitimate smoking-related cost because it's fraudulent. It's, nonetheless, a cost of treatment.

Now, I'm not suggesting that an asthmatic who is uncomfortable is fraudulently seeking treatment. What I'm saying is that

they're seeking treatment at a higher rate, quite possibly unnecessarily, and is that -- in my mind that is probably not a legitimate cigarette-related cost. Does that clarify it at all for you?

Q. Even in the hypothetical absence of smoking, all other things remaining constant, those costs would be lower?

A. Yes. My hypothetical to your hypothetical added on the notion of someone seeking treatment fraudulently, for example. And, if someone is seeking treatment that is not necessary, simply because of some extra discomfort, whether it's itchy skin or just a general malaise, that to my mind is not a legitimate cigarette-related cost that you can fractionate out and say that is caused by smoking.

It may be caused by a number of things, smoking being only one of them. There's no way to really know what portion of that is due to smoking, even though there's a distinct difference between a smoking population and a nonsmoking population. There may be other differences in those households between

nonsmoking and smoking households that account for that additional discomfort.

Q. Confining our discussion here to disease incidence in persons who are themselves smokers and to the list of the diseases in what I imagine is Exhibit 2, at page 150 --

A. What are we talking about, are we talking about the Surgeon General's report?

Q. Yes.

A. I think you took that away from me.

Q. Can you indicate to me given those constraints which of these diseases you're referring to as being aggravated by rather than caused by smoking?

MR. DUNCAN: Objection as to form.

THE WITNESS: Certainly in the other respiratory disease category and possibly in the other heart disease category with respect to something like congestive heart failure.

BY MR. PICCIONI:

Q. So that's not true, for example, about lung cancer?

A. In all likelihood not.

Q. Why is that, why is it not?

A. Because, when people are under

treatment for lung cancer, they're under treatment for lung cancer. In most cases they're not seeking medical treatment simply because their anxiety level happens to be a little higher. They've already been diagnosed.

I'm talking about conditions that people can live a long time with such as congestive heart failure and asthma and perhaps a variety, chronic pleurisy, things of that nature.

Q. Let's say, for example, coronary heart disease. And, considering research which indicates to some people that the incidence of coronary heart disease in a population is associated with a variety of different risk factors, are you saying that, if smoking interacts with those other risk factors, the excess number of cases observed in smoking populations versus nonsmoking populations is not attributable to smoking?

A. No, because here you're talking about what constitutes putatively diseases that are caused by smoking. I'm talking here about diseases that are only aggravated by smoking but that are not caused by smoking or not reputed to be caused by smoking.

Q. If you have a population of people who are exposed to asbestos and you subdivide that population into two halves, the half that smokes and the half that doesn't by some definition of smoking, and you observe a higher mortality from lung cancer among the smoking asbestos workers in comparison to the nonsmoking asbestos workers, is that an example of a situation in which you would say that smoking is aggravating a condition rather than causing it?

A. No, that's not what I was getting at here. I was getting at conditions which are not normally by themselves considered terminal, conditions that tend more to be chronic and cause some degree of suffering, but not necessarily conditions such as lung cancer brought on by asbestos or asbestosis itself being aggravated by this, where you've got a terminal condition.

I was talking about more the minor conditions. Not that congestive heart failure is necessarily minor, but it is much less problematic than other heart conditions one can suffer.

(Recess.)

MR. PICCIONI: Back on the record.

BY MR. PICCIONI:

Q. Doctor, we were talking about product safety. I asked you whether you could think of products that were in some respects less safe now than they were 25 years ago. Do you recall those questions?

A. Yes.

Q. If we confine the question to products that are used in the same way as they were 25 years ago, can you give me some examples of products that are less safe than they were 25 years ago?

A. Not off the top of my head. With reflection I might be able to.

Q. Can you give me examples besides chain saws of products that are safer now than they were 25 years ago in that same sense, with the same use, pattern of use?

A. Yes. I think infant cribs would be a good example.

Q. Automobiles?

A. With automobiles we've kind of traded a headache for an upset stomach. I'm not sure that they're all that much safer. We have a lot of safety devices in them, but people still seem to

be able to get themselves into trouble. And I think the recent emergence of air bag injuries to small children is a reasonable example of a safety feature that wasn't necessarily safe for everybody.

Q. But on balance an improvement in safety or a detriment to safety, the air bag?

A. On balance an improvement.

Q. Pharmaceutical drugs?

A. I don't know much about pharmaceutical drugs.

Q. What do national statistics suggest about the per capita occurrence of injuries caused by products show in terms of a trend over time, over the last 25 years?

MR. DUNCAN: Objection as to form.

THE WITNESS: Deaths?

BY MR. PICCIONI:

Q. We could look at deaths, sure.

A. A reduction in deaths -- one has to be very careful in looking at the data with a broad array of things such as products because different exposures have different ways of measuring them.

But, if you just talk about crude

numbers per product out there, there's been some reduction in deaths. But that's more a function of better treatment than it is necessarily safer products, because new products are coming on the market constantly.

Q. Same question but as to injuries?

A. Probably pretty much the same as it was. Injuries have moved since the turn of the century from seventh leading -- well, this is deaths. But seventh leading cause of death to fourth. But that's because others have increased. Injuries have been roughly 30 million a year. Hospital emergency room treated injuries for the last 20 years hasn't shown any real strong trend upwards or downwards.

Q. That's with an increase in the population?

A. That's with an increase in the population. But over 20 years the increase hasn't been that substantial. You're talking about between 28 and 33 million injuries a year. And injuries are distributed kind of randomly in the population. So it's a little difficult to really pin it down.

Q. So are you saying that it's the rare

instance to find a product for which design changes over the past 25 years have improved safety?

MR. DUNCAN: Objection as to form.

THE WITNESS: That's not what I said. I think that improving safety for individual products has been a goal and probably an achievement of many in the field. But there are new products coming out on the market constantly that simply regenerate a whole new generation of accidents.

BY MR. PICCIONI:

Q. So, as to products that existed before and still exist now, it is an achievement in the field?

MR. DUNCAN: Objection as to form.

THE WITNESS: Yes, I would say it is.

BY MR. PICCIONI:

Q. Doctor, is it your opinion that there is no safe level of lead in paint?

MR. DUNCAN: Objection as foundation.

THE WITNESS: It's my opinion that you cannot identify a level of lead in paint that is safe, that's correct.

BY MR. PICCIONI:

Q. Just to address counsel's objection, if you can refer to your report in the Minnesota case, at pages 14 and 15, am I correct that you're giving as an example of something an episode involving the setting of permissible levels of lead in paint?

A. That's correct.

Q. That's a section that is not in the Ohio report, is that correct?

A. It probably isn't. I think I dropped that out after the first two or three reports. It's, nonetheless, true.

Q. Are there other reports besides the Minnesota, the Washington Laborers case, and the Ohio Iron Workers case?

MR. DUNCAN: Objection as to form.

THE WITNESS: I'm trying to remember if we did a report for Texas. I think we did a report for Texas.

BY MR. PICCIONI:

Q. So you understood my question to refer to reports prepared under your direction and as part of your participation as an expert witness?

A. Yes.

MR. PICCIONI: We'd like that report

produced, if possible.

MR. DUNCAN: Was that part of the agreement, do you recall?

MR. PICCIONI: Good question.

BY MR. PICCIONI:

Q. Is there a sense in which you rely upon any research or investigation performed for the creation of the Texas report in your report submitted in Ohio?

A. No. Do you mean separate research?

Q. In other words, is there any effort that was expended on your part in producing the Texas report that also contributed to the creation of your report in Ohio?

MR. DUNCAN: Objection as to form.

THE WITNESS: I really -- each report built on the previous reports to the extent there were common areas of concern. It depends on what the model was that was being used. But it was not separate research, it was separate review of documents and statements made with reference to those documents.

BY MR. PICCIONI:

Q. So, to the extent there were common areas of concern, the Ohio report built on the

Texas report?

A. It was built from the same -- the review of much of the same material as the Texas report. Was there a separate report? I really can't recall which one we actually did a written report for. I don't know if Texas did a summary or Mississippi did a summary, but it was one of those two. That was a year or so ago, it's tough to remember.

Q. But prior to the Ohio report?

A. Yes.

Q. Doctor, you make the statement somewhere in your report I believe, correct me if I'm wrong, that CPS II was not intended to be applied to populations below the national level; is that correct?

A. That's correct.

Q. Has it been applied to populations below the national level other than in the context of either the Northwest Laborers case, the Ohio Iron Workers case, any of the Attorney General's Medicaid reimbursement cases?

A. To the best of my knowledge, no. It may have been, but I don't know.

Q. Are you familiar with the SAMMEC

program developed by the Centers for Disease Control?

A. Yes.

Q. Is it your understanding that one of the purposes of that program was to enable subnational entities to develop their own estimates of smoking attributable mortality?

A. Yes.

Q. And does that component of SAMMEC rely upon the data obtained from the CPS II study?

A. I think, to the extent that it documents the need through use of the Surgeon General's report which is national data, yes. I'm trying to remember back whether or not they tried to take those figures and plug them in directly. I don't think they do.

Q. Well, let's just take it as a premise that the way that the mortality component of SAMMEC works is that the mortality ratios from the CPS II data that's published in the 1989 Surgeon General's report is put together with estimates of smoking prevalence and applied to deaths for the respective diseases. Would you say that that is using CPS II data on a subnational population?

A. Yes, I would.

Q. So, to the extent to which that was a decision -- strike that.

The extent to which the design of SAMMEC reflects a decision on the part of the Centers For Disease Control that CPS II results are applicable on a subnational level, you would disagree with it?

A. That's correct.

Q. To the extent to which the Surgeon General of the United States has issued the statement that smoking is a major cause of lung cancer, you would disagree with it?

A. That's correct.

Q. To the extent to which the World Health Organization through the International Agency for Research on Cancer has issued statements that smoking is a major cause of lung cancer, you would disagree?

A. I would.

Q. To the extent to which the National Cancer Institute has issued statements that lung cancer -- strike that. That smoking is a major cause of lung cancer, you would disagree with that?

A. I would. I would say in each case that it may be a cause of lung cancer.

Q. And that statement, it may be a cause of lung cancer, is different from the statements that I have been describing?

A. Yes.

Q. Similarly, as to statements regarding the causal relationship between smoking and lung cancer issued by the American Cancer Society, you would disagree?

A. Is that the same group you mentioned before?

Q. I didn't think I had mentioned the American Cancer Society.

A. I'm not sure what the precise statement is they make.

Q. If that statement is smoking is a major cause of lung cancer in the United States, you would disagree?

A. I would disagree and say that it may be.

Q. I won't go through the list again. But would you have a similar answer if I simply replaced the phrase lung cancer with coronary heart disease?

A. Yes, I would.
Q. Outside of the context of litigation, have you expressed these opinions in writing?
A. I don't think so, no.
Q. And by these opinions you understand --
A. The opinions that we just discussed, my opinion that it may be a cause of cancer or heart disease.
Q. Rather than is a major cause of?
A. I don't recall writing anything in that context.
Q. Have you ever expressed these opinions to any of the epidemiologists who you mentioned personally knowing at the beginning of the deposition?
A. I don't think so, because I have known them all in a relationship that goes back several years. And the only one I've seen within the past year has been David Savitz.
Q. And you didn't tell David Savitz that you disagree with the Surgeon General of the United States when he said smoking is a major cause of lung cancer and heart disease?
A. It didn't come up. I was down there to give a lecture on survey methods.

Q. Would you agree that the issue of whether smoking is a major cause of lung cancer and heart disease in the United States is one that concerns the epidemiological community?

A. That question took so long to get out, I wish you would put it together for me.

Q. Is it an important issue to epidemiologists?

A. Whether or not smoking is a cause --

Q. Whether or not smoking is a major cause of lung cancer.

A. I think it's something the entire medical community is concerned about, yes.

Q. But specifically those who are concerned with epidemiological methods, is it an important issue to them?

MR. DUNCAN: Objection as to form.

THE WITNESS: You'll have to tell me what you mean by issue to them. In what context would it be an issue to them?

BY MR. PICCIONI:

Q. That it matters to their thinking about epidemiology whether or not the Surgeon General or all of these other agencies are wrong when they say that smoking has been shown to be a

major cause of lung cancer and heart disease?

MR. DUNCAN: Objection as to form.

THE WITNESS: I think I can speak not for the epidemiologic community. I can speak for myself as a practicing epidemiologist, that any question such as that is a major issue. But the importance of being precise about it is largely a function of the use to which it's to be put.

If it is to be used to decide whether or not you want to develop remedial programs and do you want to have a smoking sensation -- cessation program be a part of a general health policy, that is a rather inonerous kind of use to which you're putting this, because individual decisions will be made by practitioners in the public health arts on down through the chain as to whether or not that's going to be a part of their day-to-day operations and how much of their resources they're going to devote to it.

If, on the other hand, you are talking about something in a more -- with a more draconian result such as regulation, which I spent 20 odd years at a regulatory agency, or banning or restitution, anything where somebody who is responsible in that process is going to be

assessed in some way for their role, then I personally feel it's absolutely essential that you be on very firm ground and that you know whereof you speak.

And this is why I tend to draw this distinction rather consistently, about not wanting to agree that smoking is the cause nor even a cause of a disease when I know there are other causes for that disease. I would say pin that down for me and I will agree. But absent that I cannot go beyond in my own mind thinking that it may be and it warrants further exploration.

BY MR. PICCIONI:

Q. Am I correct in understanding that your response is consistent with the following, in the context of civil litigation for reimbursement of millions of dollars of healthcare expenditures, the standard of proof required is high?

MR. DUNCAN: Objection as calling for a legal conclusion.

THE WITNESS: I don't know what high means. But I expect more proof than if something is simply going to be used to develop a program or a project, whether it's a national program or

project or a local program or project.

BY MR. PICCIONI:

Q. Higher than a better than even chance?

MR. DUNCAN: Same objection.

THE WITNESS: I can't put that kind of a criterion on it.

BY MR. PICCIONI:

Q. If those who are convinced that there is a causal relationship between smoking and lung cancer and coronary heart disease are wrong, would that impact research into epidemiological methods?

MR. DUNCAN: Objection as to form.

THE WITNESS: I'm trying to put the question together again. It's a question with a lot of time between the beginning and the end.

If those who believe that smoking causes lung cancer and coronary heart disease are wrong, would that impact resources dedicated to epidemiology research?

BY MR. PICCIONI:

Q. No. Would it impact the thinking of epidemiologists about epidemiological methods.

MR. DUNCAN: Objection as to form.

BY MR. PICCIONI:

Q. Their validity, their utility?

A. I think it would, especially with respect to the use of things such as attributable risk in this context which carries with it the requirement that all else be equal. And most of them know for a fact that all they can do is adjust for that statistically. They don't know in point of fact that all else is equal.

Q. Would you disagree with the proposition that the overwhelming majority of practicing epidemiologists in the United States are persuaded that the relationship between smoking and lung cancer on the one hand, coronary heart disease on the other, has been established as more likely true than not true?

MR. DUNCAN: Objection as to form. To the extent that the witness knows, he can answer.

THE WITNESS: I don't know what the overwhelming majority may believe in the context of this litigation. I think the majority of people I know in this field, as I alluded earlier, are inclined to set a higher standard for proof when there is a draconian action contemplated than if it's merely for program

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guidance.

BY MR. PICCIONI:

Q. I attempted in my question to set what that standard of proof was which was more probably true than not true. Does that enable to you answer the question?

MR. DUNCAN: Objection as calling for a legal conclusion.

THE WITNESS: No, because -- I cannot put a more probably than not on it. Most of us in this field would like to be sure of the ground we stand on before we do something.

I can speak only for the background I have in regulatory agencies; that, as the director of epidemiology, I wanted to be absolutely certain that we had proof of cause and effect before we banned or changed a product.

BY MR. PICCIONI:

Q. Can you name for me a single epidemiologist practicing in the United States today who you know is of the opinion that smoking has not been shown on a more likely than not basis to be a cause of lung cancer?

A. I know of one.

Q. Can you think of another one?

A. I know others with whom I've spoken agree with the position I have taken in the context in which I have taken it. And they are practicing epidemiologists who cannot speak up publicly because it is politically incorrect for them to do so and their careers would be destroyed.

Q. And you interpret what they said to mean what I asked, that smoking has not been shown on a more probable than not basis to be a cause of lung cancer?

A. That's not quite the way the conversation lined up. So the answer to that question is no.

Q. The issue in these conversations that you're making reference to had more to do with the applicable standard of proof; is that correct?

A. It had more to do with what I do for a living. Tobacco litigation comprises a reasonably substantial part of my income. And they're curious as to what my stance is. I have shared it with them. And they with no exceptions have accepted my reasoning.

Q. Have?

A. Accepted my reasoning.

Q. In your Ohio report, Doctor, Exhibit 1, at page 11, the first full paragraph on that page ends with a sentence. Could you read that sentence. It starts with it is inconsistent.

A. Yeah, I'm just looking at the context. "It is inconsistent with the scientific method and fallacious reasoning simply to assume that either risk factor prevalence rates or relative risks are the same in two discrete populations without demonstrating empirically that they are the same."

Q. That sentence is new to the Ohio report in the sense that it's not in the Northwest Laborers report?

MR. DUNCAN: Objection as to form.

THE WITNESS: It may be. I don't think in the Northwest Laborers report I discuss CPS II. I don't think anyway.

BY MR. PICCIONI:

Q. Forgive me for asking this question, but that wording is entirely your own?

A. Yes.

Q. Is it inconsistent with the scientific method and fallacious reasoning to assume that

either risk factor prevalence rates or relative risks are similar in two discrete populations without demonstrating empirically that they are?

A. Why are you saying similar?

Q. I'm asking a question, whether you agree with that statement.

A. It depends on the degree of similarity, if similarity means for all practical purposes the same.

Q. Then would it be inconsistent with the scientific method and fallacious reasoning to assume that they are similar in two discrete populations without demonstrating empirically that's the case?

A. Yes, I think you have to take a look at what the source of the information is, what the derivation of the risk factors are, and whether or not they're comparable.

Q. Are any of the results from the NEISS system used to reach conclusions that are applied to populations that are not part of the NEISS study?

A. Are any of the --

THE REPORTER: "Question: Are any of the results from the NEISS system used to reach

conclusions that are applied to populations that are not part of the NEISS study?"

THE WITNESS: No. NEISS doesn't really lead to conclusions. NEISS is a case identifying system essentially. It allows us to draw some appreciation of what products are being treated in hospital emergency rooms and it's used as a form of administrative triage by that federal agency and others who have bought into the system to make a determination where they want to zero in and take a closer look. But there are no conclusions as to cause ever derived from NEISS.

BY MR. PICCIONI:

Q. But there are conclusions about where to spend limited resources?

A. Where to look further, yes.

Q. And spend money that could be spent elsewhere?

A. Well, you have to understand the way the Consumer Products Safety Commission operates. By looking further you go to the second level of NEISS. There's a budget set aside within the Consumer Products Safety Commission for in-depth investigative follow-up. And judgments will be made from NEISS

based upon either the frequency of a particular event coming in from the hospitals which are a statistically valid set of hospital emergency rooms across the nation to select a sample of cases associated with a product that is very frequently involved or a product that is involved perhaps less frequently but with more serious injuries.

Some of that investigative budget will be applied to those to gather additional information. Sometimes the information will be quite simple; for example, to determine more precisely the product that's involved. Since there is an estimated ten to 15,000 products that the commission is regulating, it's necessary to have product codes which cover a wide variety of them.

And originally, for example, we had a code for recreational vehicle. It was only when we saw the size of recreational vehicle injuries being reported through the system increasing rapidly that we created additional codes to get greater precision and determine what kinds of recreational vehicles. That's the nature of the additional resources that are being spent.

Once decisions are made as to whether or not a product has a definable role in the creation of an accident or an injury, a decision will be made based upon those data which usually are predicated on a combination of the surveillance investigations and some engineering studies and a recommendation will be made to the commission who will make a decision.

And that decision will be predicated partly on the data, partly on the politics of the situation, and partly on the ability to do something fairly rapidly about it.

Q. But in that process are the participants limited to making decisions that affect the populations under study by the NEISS system; in other words, aren't they making decisions that are based upon the inference that observations made by the NEISS system or follow-up observations based on other limited populations apply generally to the U.S. population?

A. No. They apply generally to the product that's being looked at.

Q. A product in the hands of consumers generally in the United States?

A. Yes.

Q. So you don't, for example, say the NEISS system is telling us that we're treating an awful lot of kids for lawn dart injuries, but we only know about the kids who are being treated in the hospitals that are part of the system, we know nothing about the kids that are being treated in other hospitals?

MR. DUNCAN: Objection as to form.

THE WITNESS: That's not true. The NEISS is a weighted probability sample. And as such the cases that are reported through the hospitals that participate in NEISS are representative of cases being reported through other hospitals.

BY MR. PICCIONI:

Q. Are they inferred to be exactly the same as the cases that would be reported through the other hospitals?

A. No.

Q. Would epidemiology be useful if the results of an epidemiological study only applied to the subjects of that study?

A. By subjects now are you talking about the products or the victims?

Q. The study subjects.

A. The study subjects are the products.

Q. Speaking more generally about epidemiology as a science.

A. Well, I can't make the leap that you're making then from the general science of epidemiology to the subjects of people or injuries reported through the NEISS. You'll have to draw that distinction for me, I can't follow your question.

Q. I'm speaking generally about epidemiology as a science and asking you if the utility of epidemiology as a science is not based on the belief of epidemiologists that epidemiological findings obtained from the study of one population are applicable to other populations?

A. To the extent that the study population is statistically representative of the rest of the population, of course it is.

Q. How do you decide whether the two populations have that relationship, that the one is statistically representative of the other briefly?

A. Well, generally one has to be a

specifically selected subset of the other. If you take two statistically valid samples in the United States, they're not necessarily subsets of one another, but they are both representative sets of the master set which they're looking at.

In that case they probably can be viewed in a joint context, but they are statistically representative of some larger group that they're looking at, both of them in that case.

Q. So it's based upon the fact that the one is a random sample from the other; am I understanding this correctly?

A. Not necessarily a random sample -- that the smaller population is a random sampling of the other?

Q. Yes.

A. A statistically representative sample, random is one way to get at that.

Q. And does the judgment that the one population is statistically representative of the other require specifying the degree of precision required in the application of the results from the one population to the other population?

MR. DUNCAN: Objection to form.

THE REPORTER: "Question: And does the judgment that the one population is statistically representative of the other require specifying the degree of precision required in the application of the results from the one population to the other population?"

THE WITNESS: I'm still not sure I understand that question.

BY MR. PICCIONI:

Q. Sure. Let me give you an example. Suppose the question is a qualitative one, is the incidence of lung cancer higher in asbestos workers versus other workers. And you have an observation of lung cancer in asbestos exposure in one population, but you want to answer that question, that qualitative question, about another population.

Am I right that that would require considerations of statistical representativeness that are different than the situation where you wanted to develop an estimate of the statistical association between asbestos exposure and disease in that second population that was precise to 1 percent?

MR. DUNCAN: Objection as to form.

THE WITNESS: I'm sorry, but this question is just so convoluted I can't quite make out what your precise question is. Is there some way you can simplify it for me?

BY MR. PICCIONI:

Q. Sure, I will certainly try.

Don't we all extrapolate our experiences made in one set of observations to future events or events that take place under other circumstances?

MR. DUNCAN: Objection as to the form.

THE WITNESS: I can't say what we all do. From time to time, I do, yes.

BY MR. PICCIONI:

Q. But, when a more precise answer is required, we have to be more careful?

A. Yes.

Q. And part of what we have to be careful about is whether our observations were made under circumstances that are representative of the circumstances that we want to apply that to?

A. Yes.

Q. So the degree of care that we have to exercise or should exercise in your view in taking observations from one context and applying

them to another depends upon the degree of precision that we're asking for in the answer?

A. Yes, and the importance of the decision that you make in the other condition. If it's shall I go to the golf course or shall I go sailing, it's not quite as important as should I invest my money here or should I invest my money there.

Q. So is it necessarily then inconsistent with the scientific method and fallacious reasoning to assume that risk factor prevalence or relative risks are similar in two discrete populations without demonstrating empirically that that's the case regardless of the degree of precision required of the comparison?

A. To my mind it's more or less important depending on the application to be used. But, if you're going to apply what you call a scientific method or suggest that you're doing any kind of analysis before making your decision, then it should, in fact, be an analysis, it shouldn't be just, oh, it looks the same here and it looks the same there and let's go with it.

I wouldn't even do that in trying to decide at a local county level whether or not I

wanted to have a representative on the local safety council or a representative on the city council on that cavalier a basis.

I would try to decide what's more important to me as an organization and how much analysis would I have to do to decide where's the best place to put my resource at that point. So I think in science it's a good deal different than everyday life.

Q. But if the question that's being posed to the scientist is a question that inherently does not require a precise answer, is it inconsistent with the scientific method or fallacious reasoning to use a methodology that meets the precisional needs of that question?

MR. DUNCAN: Objection. Counsel has asked that question about five times including the times before. He still doesn't agree with the way you're asking. I think it's been asked and answered.

THE WITNESS: I can only say that, in the scenario you're drawing here, if the decision is a minor administrative decision, it probably would not be inconsistent.

But the context of this sentence is

after discussion of Ohio Funds and the CPS II population. So the context of the sentence here is what I had in -- the context of the preceding sentence is what I had in mind when I wrote this. And I stand behind the statement.

BY MR. PICCIONI:

Q. And so the statement is to be read in the context of your understanding of the degree of precision required of this, the plaintiffs' damages model?

MR. DUNCAN: Objection, misstates his testimony.

THE WITNESS: I'm talking about here differences in the population in the Ohio Fund which are predominantly union members as opposed to the CPS II population which are predominantly middle to upper middle class white population with a well above average education.

And these two populations are -- one clear difference. And I'll warrant there are several others that we could document. I say, if you're going to analyze these data for any scientific purpose, you should try to demonstrate empirically that they are the same or precisely how they differ so that you can try to adjust for

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them.

(Recess.)

MR. PICCIONI: Back on the record.

BY MR. PICCIONI:

Q. Doctor, when we were discussing before what would be involved in doing a study of expenditures in these funds, we were talking solely about the issue of the accuracy of coding of ICD-9 disease categories; is that correct?

A. Well, not really. I mean that's the context in which the discussion came up. But we're talking about the total array of data. The accuracy of the ICD-9 categories is certainly one part of it. The accuracy of information on smoking through the National Center for Health Statistics may also be a question because that didn't necessarily break down to what the smoking habits may be within that population.

So I would say that it would be best to know as much as you can about the two populations. As far as the ICD coding goes, we were talking about investigating individual patients' medical records and so on. But it would be best if all of the data were very

specific to the population, the target population.

Q. Your estimates of the amount of effort involved pertain to the ICD-9 code checks?

A. Yes, largely.

(Verhalen-Ohio Exhibit No. 4 was marked for identification.)

BY MR. PICCIONI:

Q. Doctor, one of the papers that you cite I believe in your report is a study, the first author is Barendregt?

A. Yes, the New England Journal of Medicine, a study entitled The Health Care Costs of Smoking.

Q. Doctor, on page 1054 there is a figure entitled Estimated Annual per Capita Health Care Costs for Dutch Men in 1988 and for the Male Population in a Life Table, According to Age and Smoking Status; is that correct?

A. Yes.

Q. Is this figure pertinent to the issue that this paper addresses, that is the reason why you included it as one of your references?

A. The direct reference of information in this article is less germane to any specific

point in here than it might have been to an earlier report. Many of these reports as I said are covering the same ground.

And for the most part I am putting in my bibliography articles that were reviewed and are a part of my total background of knowledge on these kinds of things when I come into these studies. I cannot without reading it bring a specific point out of here and point to it in the study.

Q. So looking at this figure does not bring to mind the reason why you cited this paper?

A. No, it doesn't, it doesn't leap out. The reason it was cited was because it was part of the literature that we kept for this study and two or three previous studies. I don't feel it's appropriate to pull something out simply because it's not very specifically germane to an issue when it is a part of the total background.

Q. But there isn't any particular statement or proposition in your report that the Barendregt paper supports?

A. Not that come to mind immediately. I would have to look at the article again.

As I review the abstract, by way of just trying to remind myself of what the details of the article are, no, this was part of the total background package, the point in this being one that nobody really likes to talk about openly, and that is that, if you did actually stop all smoking, healthcare costs in total might go up. But that's not an argument I'm trying to make here.

Q. Why would they go up?

A. Because people live longer and they use the medical care delivery system for many more years than do smokers by and large. Smokers have an earlier age of death.

Q. I don't understand. Why would the costs -- under what circumstances would they go up?

A. Because people live longer and at an older age they tend to use the medical care delivery system more than they did at a younger age and the total healthcare costs would be as high or higher than they would be than the smoking costs normally.

It's not an argument that I'm trying to make here, but it's an article that I thought was

interesting and I thought creates a very interesting economic point. But I'm not an economist, I'm not trying to promote this particular position as a part of my --

Q. I'm just trying to understand what you said and I'm a little confused.

A. Healthcare costs for smokers -- let me read from the document.

Q. Yeah.

A. "Health care costs for smokers at a given age are as much as 40 percent higher than those for nonsmokers, but in a population in which no one smoked the costs would be 7 percent higher among men and 4 percent higher among women than the costs in the current mixed population of smokers and nonsmokers. If all smokers quit, health care costs would be lower at first, but after 15 years they would become higher than present. In the long term, complete smoking cessation would produce a net increase in health care costs, but it could still be seen as economically favorable under reasonable assumptions of discount rate and evaluation period."

The conclusion is that, if people

stopped smoking, there would be a savings in healthcare costs but only in the short term. Eventually smoking sensation may lead to an increased healthcare cost. It's an interesting economic argument.

Q. When you said sensation, do you mean cessation?

A. Cessation, that's what I thought I said.

Q. Now, healthcare costs in the long run then you are saying would go up if people stopped smoking?

A. That's correct, total healthcare costs for the population.

Q. And they would go up --

A. According to Barendregt, if people stopped smoking, there could be a savings in healthcare costs, but only in the short term. Eventually smoking cessation would lead to increased healthcare costs.

This is an argument nobody really likes to promote because it sounds crass, and a reason for objecting to some of the things that are going on here may be to present the argument that it actually costs more to keep people alive

longer than to let them die younger.

To the extent that smoking may or may not be responsible for that, it's a fact that the longer one lives, the higher one's healthcare costs go, just a basic economic fact of life apparently.

Q. Can we look at that figure, figure 1 on page 1054.

A. Yes.

Q. Is the concept that you were just describing to me reflected in something like the area under those two curves that go up and then come back down?

A. Yes.

Q. And why does the dotted curve come down before the one with the solid lines?

A. Well, you're talking about the age group. If you look across the bottom, you've got age bands ranging from 40 on up to 89. You've got fewer people remaining in the population requiring medical costs at age 75-79 among smokers than you do among nonsmokers.

You're talking about an annual population cost per capita of around $4,500 with a total population cost of around $600 million

for 75 to 79-year-olds, in a year for which the nonsmokers among that group would be totaling close to $900 million or roughly $7,000 per person.

Q. The dotted line represents the smokers, the solid line the nonsmokers?

A. That's correct.

Q. And the dotted line drops down earlier than the solid line?

A. That's correct.

Q. And that reflects what phenomenon?

A. That reflects an earlier death among smokers than among nonsmokers. Once someone dies, they no longer have medical costs. Those who survive continue having medical costs. And they continue to increase to a high up around age 75-79 and then they begin to drop off.

Q. What would happen to the areas -- excuse me.

And the total population costs are represented by the areas under these two curves; is that correct?

A. That's generally the way one views these. These are really midpoints of bar graphs. Essentially, when you have a line chart

like this, it's a form of histogram.

Q. Now, what would happen to the areas under these two curves, the one for the smokers and the one for the nonsmokers, if at the age of 65 all expenditures were reduced by 80 percent?

A. I don't know, I'm not an economist. I mean I could hazard a guess, but that's outside of my field.

Q. But just simply, if you numerically look at this chart and just take every point that lies to the right of age 65 and drop it down to one-fifth of its value, how would the areas under those curves compare?

MR. DUNCAN: Objection, asked and answered.

THE WITNESS: I mean I can only say what I said before, I'm not an economist. Anything I would do would be conjecture, it's outside of my field, because you really have to understand this to get into discount rates and everything else, if you want to do that. And I'm not in a position to try to do any of that.

BY MR. PICCIONI:

Q. But the reason graphically, is this correct, that the area under the solid curve, the

one for nonsmokers, is greater than the area under the dotted curve for smokers because the area between the solid curve and the dotted curve after 65 is greater than the area between the dotted curve and the solid curve before 65; isn't that true?

A. It may be. The shapes of the curves would be again as I said the subject of some conjecture. So I'm not sure exactly what would happen. But, if you were to decrease costs by 85 percent, I presume you mean by 85 percent for smokers?

Q. No, for both. And it's 80 percent for both.

A. And why would you want to do that?

Q. I'm just asking the question.

MR. DUNCAN: And it's been asked and answered, objection.

THE WITNESS: I don't know. I'm really not in a position to try to project these numbers. I mean presumably everything would come down, but I don't know how close the lines would be or anything else. I would probably want to do some arithmetic and draw a fresh chart. Perhaps you can see it, I can't.

BY MR. PICCIONI:

Q. Well, the peak value for the nonsmokers is roughly at what age?

A. Seventy-five to 79.

Q. And the value is?

A. $7,000 per capita, $900 million population.

Q. So let's look at the population cost of 900 million. Just for the purposes of this question, decrease that value to one-fifth of that.

A. Which value?

Q. The close to $900 million for the population.

A. All right. Decrease it by 80 percent?

Q. Yes.

A. All right.

Q. And so on for each of the data points for both the nonsmokers and the smokers for all ages past 65.

MR. DUNCAN: Objection. Counsel, you've asked this question, he said he doesn't feel comfortable doing it, you've asked it numerous times, asked and answered.

BY MR. PICCIONI:

Q. You can answer.

A. I don't know, when I'm doing that, what I'm doing to the numbers. I may be doing violence to some economic theory. I'm not in a position to try and do something like that and make sense out of it.

Q. I'm only asking you a question about this figure graphically. Graphically what would happen to the area under those curves if you did that?

A. They would both decrease.

Q. And would it still be true that, for the whole period between age 40 and age 89, the area under the solid curve would be greater than the area under the dotted curve?

A. I have no idea. It might be. But it might be closer, the two lines might be much closer together. I don't know. Intuitively it makes sense, but this is outside of my knowledge.

Q. In this chart per capita costs are always greater for smokers than nonsmokers, is that true, at all ages?

A. Per capita costs, no, not in all ages, because for smokers it's dropping considerably

after age 64.

Q. Per capita costs.

A. Yes. If you look at the left, it says per capita costs. And that number is going down on the dotted line.

Q. Let's make sure we're looking at the same lines. I'm looking at the --

A. Okay. I'm sorry. I was looking at the population cost curve. Per capita costs are higher overall, yes.

Q. For all ages?

A. Yes.

Q. For the smokers.

We can go off the record.

(Discussion off the record.)

MR. PICCIONI: Let's go on the record. We're marking Dr. Verhalen's report in the Minnesota case as an exhibit, Exhibit 5.

(Verhalen-Ohio Exhibit No. 5 was marked for identification.)

MR. PICCIONI: I'm done.

(Whereupon, at 4:35 p.m., the taking of the instant deposition ceased.)

_____

Signature of the Witness

SUBSCRIBED AND SWORN to before me this _____ day of _____, 19__.

_____

NOTARY PUBLIC

My Commission expires: _____

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